Reducing Dynamic Foot Pressures in High-Risk Diabetic Subjects With Foot Ulcerations

A comparison of treatments

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OBJECTIVE — To compare the effectiveness of total contact casts, commercially available therapeutic shoes, and removable walking casts to reduce mean peak plantar foot pressures at the site of neuropathic ulcerations in diabetic subjects.

RESEARCH DESIGN AND METHODS — We compared the reduction in peak plantar pressures at ulcer sites under the great toe ($n = 5$), first metatarsal ($n = 10$), and second through fifth metatarsals ($n = 10$) using six treatments: total contact casts (TCCs), DH Pressure Relief Walkers (DH), Aircast Pneumatic Walkers, Three D Dura-Steppers (3D), CAM Walkers, and P.W. Minor Xtra Depth shoes. A rubber sole canvas oxford was used to establish baseline pressure values. The canvas oxford could be viewed as a worse-case scenario for this patient population. With the EMED Pedar in-shoe pressure measurement system, data for 40 steps were collected for each treatment. We used Tukey's Studentized Range Test for simultaneous multiple comparisons to compare treatments.

RESULTS — DH Pressure Relief Walkers reduced plantar pressures significantly better than other commercially available treatments for ulcers under the first metatarsal, second through fifth metatarsals, and great toe ($P < 0.05$). There was not a significant difference in mean peak plantar pressures between TCCs and DHs at any of the forefoot ulcer sites.

CONCLUSIONS — DH Pressure Relief Walkers were as effective as total contact casts to reduce foot pressures at ulcer sites and may be an effective practical addition in the treatment of foot ulcers.

Ulcerations are one of the most common underlying causes of amputation in people with diabetes (1). These ulcerations are commonly associated with peripheral neuropathy and occur in areas on the plantar surface of the foot that are exposed to constant or repetitive pressure during normal activity (2,3). Ulcer healing can often be achieved by decreasing the pressure affecting the ulcer site or by decreasing the number of cycles of exposure (the number of steps per day) (3).

Recommendations to eliminate foot pressures with bed rest or crutch-assisted gait are often impossible or impractical for patients to use for the 4–12 week period generally required for an ulcer to heal. The ability to offload the ulcerated foot with crutches is often a physical impossibility because of the presence of obesity, limited cardiovascular reserves, poor upper body strength, unsteadiness, and visual impairment in people with diabetes. In addition, because patients with neuropathic ulcers do not experience pain or other adverse symptoms, they tend to ignore their wounds and continue their usual activities despite threats, coaxing, and cajoling by their physician or warnings of impending infection or amputation. For these reasons, treatment methods to decrease plantar pressures and heal neuropathic ulcerations should be designed for the ambulatory patient.

Total contact casts (TCCs) were popularized by Paul Brand at the Hansen's Disease Center to serve the special needs of patients with neuropathic foot wounds (4). TCCs are thought to facilitate ulcer healing by uniformly reducing pressures over the entire surface of the foot (4,5) while allowing patients to continue activities of daily living. Several descriptive studies have reported healing of chronic neuropathic ulcerations in 72–90% of people with diabetes (4–8). However, concerns about complications with this technique have limited its broad acceptance and implementation. Many physicians are hesitant to put an insensate patient in a cast that cannot be monitored on a daily basis for iatrogenic ulcers due to cast irritation, wound deterioration, or signs of infection. Also, most clinics do not have a physician or cast technician available with the time, training, or experience to properly apply a TCC. Despite their proven effectiveness and widespread popularity among diabetic foot specialists, most physicians are unable or unwilling to use TCCs.

Because of these limitations, we decided to evaluate alternative treatment methods, such as removable walking casts and therapeutic footwear. These products are commercially available and easy to quickly apply without any additional training or expertise. These alternatives, in addition to providing the same

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CVO, canvas oxford shoe; TCC, total contact cast.

EXHIBIT "B"

Table 1—*Patient characteristics*

Age (years)	58.0 ± 9.2
Duration of diabetes (years)	14.2 ± 10.2
Biothesiometer (V)	26.2 ± 10.7
BMI (kg/m^2)	29.6 ± 3.8
Diabetes type (I:II)	0:25
Sex (M:F)	23:2
Ulcer site location	
First metatarsal	10
Second through fifth metatarsals	10
Great toe	5

Data are means ± SD.

degree of pressure reduction, may offer some advantages over TCCs. Currently, no clinical or laboratory data exists to substantiate the hypothesized benefit of these treatment methods for diabetic subjects with foot ulcerations.

RESEARCH DESIGN AND METHODS— We studied 25 consecutive patients from the Podiatry Clinics at University Hospital, San Antonio, Texas, with diabetes and an existing or recently healed neuropathic ulceration on the sole of the forefoot. We used a Biothesiometer (Bio-Medical Instrument Company, Newbury, OH) to assess vibratory perception threshold using previously described criteria and methods (2,9). A description of patient characteristics is provided in Table 1.

We used the EMED Pedar in-shoe pressure measurement system to evaluate pressures on the sole of the foot (Novel, Minneapolis, MN). A description of the EMED Pedar system, components, and procedures have been previously reported (10,11). A total contact cast with a cast boot was applied using the technique described by Burnett (12) with the exception that a plywood sole was not incorporated into the last layer of plaster, and an outer layer of fiberglass cast material was applied after the total contact layer and posterior splint had been applied. This was done to allow patients to ambulate immediately after application of the cast. Patients were also tested in commercially available therapeutic footwear and four brands of removable cast walkers: P.W. Minor Xtra Depth shoe and insole (P.W. Minor & Son, Batavia, NY), DH Pressure Relief Walker (Royce Medical/Centec Orthopeadics, Camarillo, CA), Aircast Pneumatic Walker (Aircast, Summit, NJ), Three D Dura-Stepper (DeRoyal Orthopedic, Powell, TN), and CAM Walker (Zinco, Pasadena, CA). We also used a thin rubber-sole canvas oxford shoe (CVO) as a worse-case scenario to establish baseline measures for the affected foot that might be observed in patients without therapeutic footwear. An extra-depth shoe was worn on the contralateral extremity during testing with all of the modalities except the CVO. Patients were tested barefoot with all of the commercially available walkers and TCCs. A thin cotton stocking was worn in trials with footwear. In each instance, the EMED Pedar insole was placed in direct contact with the sole of the foot.

Five gait trials were performed with each treatment. To eliminate the measurements during the termination and initiation of gait, eight midgait steps were evaluated from each trial. From these trials, we measured pressure distribution from a total of 40 steps for each patient for each treatment. Treatments were evaluated in a random order. For each type of treatment, subjects were allowed to practice walking until they felt comfortable so their gait pattern would be as consistent as possible during the trial. Subjects were instructed to walk at a comfortable pace for each modality after this break-in period. For the purposes of analysis, we divided the sole of the forefoot into three regions according to the location of ulcers in the study population: first metatarsal (n = 10), second through fifth metatarsals (n = 10), and great toe (n = 5).

We used SAS for Windows version 6.10 (Cary, NC) to perform the statistical analysis of this data. To compare the effect of different removable cast walkers, footwear, and the total contact cast, we used a repeated measures design in which each patient was tested in each possible treatment. Furthermore, we measured forty replications using each treatment, using only mid-stride steps for each replication and avoiding the highly variable initial or ending steps. Therefore, we had a repeated measures design in which forty replications were nested within each treatment for each patient. To analyze the data, we used both univariate and multivariate analysis of variance procedures. To simultaneously compare differences in all treatment means, we used Tukey's multiple range tests with α = 0.05 (13).

RESULTS— Figures 1, 2, and 3 depict the mean peak pressure under the respective regions of the plantar surface of the foot with each of the treatments. Table 2 demonstrates the percentage change from baseline (CVO plantar foot pressures) for each of the treatments. DH Pressure Relief Walkers reduced mean peak plantar pressures at ulcer sites under the first metatarsal, second through fifth metatarsals, and great toe significantly better than the other commercially available removable walking casts and therapeutic footwear evaluated in this project ($P < 0.05$). There was not a significant difference between DH Pressure Relief Walkers and total contact casts at any of the forefoot ulcer sites

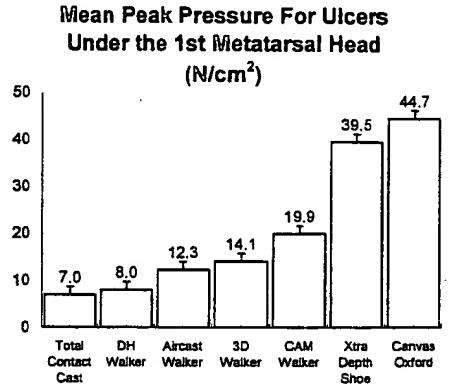

Figure 1—*Treatments are listed in ascending order based on mean peak pressures identified for ulcers located under the first metatarsal head. We identified significant differences (α = 0.05) after comparing simultaneous CIs for the following treatments: TCC = DH Walker < AIR Cast < 3D Walker < CAM Walker < Extra Depth Shoes < Canvas Oxford.*

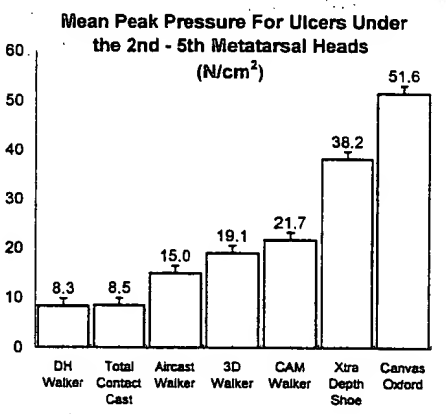

Figure 2—*Treatments are listed in ascending order based on mean peak pressures identified for ulcers located under the second through fifth metatarsal heads. We identified significant differences (α = 0.05) after comparing simultaneous CIs for the following treatments: DH Walker = TCC < AIR Cast < 3D Walker < CAM Walker < Extra Depth Shoes < Canvas Oxford.*

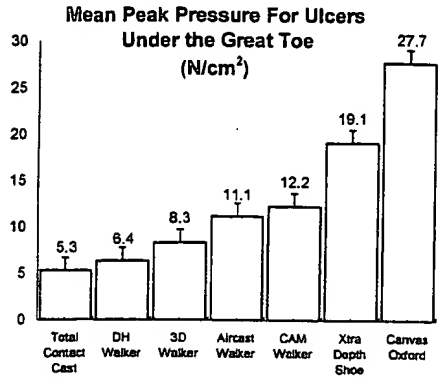

Figure 3—*Treatments are listed in ascending order based on mean peak pressures identified for ulcers located under the great toe. We identified significant differences ($\alpha = 0.05$) after comparing simultaneous CIs for the following treatments: TCC = DH Walker < 3D Walker < CAM Walker < Extra Depth Shoes < Canvas Oxford.*

($P > 0.05$). Commercially available therapeutic footwear was consistently the least effective treatment to reduce mean peak pressure at all the forefoot ulceration sites. Reducing the peak plantar pressures on the ulcer site did not increase pressures on other areas of the forefoot. In fact, all areas had mean peak pressures that were significantly less than baseline measurements in canvas oxfords ($P < 0.05$).

CONCLUSIONS — We have demonstrated that there is not a substantial difference between DH Pressure Relief Walkers and TCCs to decrease peak plantar pressures at ulcer sites under the great toe, first metatarsal head, and lesser metatarsal heads. The DH Pressure Relief Walker consistently demonstrated the greatest reduction in mean peak pressures compared with the other commercially available products we tested.

Removable walking casts have several advantages compared with TCCs that make them an attractive alternative. An effective commercially available walker will allow primary care physicians that would not usually consider serial total contact casting to treat diabetic wounds with an approach that is practical for both the patient and physician. Removable walking casts are easy to apply and remove for daily wound care and frequent inspection of the ulcer. They can be used in conjunction with therapeutic padded hosiery (14), topical enzymes, antibiotics, and growth factors as well as Unna boots or compression devices to control edema. In addition, patients can remove these types of walkers to shower and to sleep more comfortably at night. And in cases of recurrent ulceration, patients can apply a removable walker by themselves at home until they can be evaluated by their physician. The opportunity for patients to remove commercially available walking casts is one of the product's strengths as well as a potential drawback. Total contact casts provide the physician with a treatment modality that has an element of forced compliance, since the cast cannot easily be removed until the patient returns for their next appointment. Removable walking casts have the same potential for noncompliance or inappropriate use as other prescription medications or prosthetic devices and therefore require a measure of patient instruction, education, and acceptance, as would be expected with other prescription therapies. Simply put, the patient has to understand the disease process and why the constraints of a removable cast walker should be endured. In many cases, the expected long-term result of poor compliance is an even more imposing and restrictive type of permanent prosthesis after an amputation.

The DH Pressure Relief Walker may prove to be more cost effective in comparison to total contact casting. The initial cost of the walker can be realized within the first few weeks of treatment compared with the use of serial total contact casting. On average, ~6 weeks of therapy is required to heal a neuropathic ulceration with a TCC using weekly cast changes (4–8). After the initial ulceration is healed, the DH walker can be reused in cases of recurrent ulcerations. Previous studies have reported that 20–58% of diabetic subjects with healed neuropathic foot ulcerations develop another ulceration within a year (15,16). Because recidivism is so common in this high-risk population, having a durable reusable product could substantially improve the cost effectiveness of ulcer care in the short term as well as in cases of recurrence.

One of the potential limitations of this project was our inability to evaluate shear forces among the treatment modalities. Even with this constraint, this data provides insight into the potential clinical benefits of removable walking casts to heal neuropathic foot ulcerations. These products should subsequently be evaluated in clinical trials to substantiate that the observations reported from laboratory studies translate into clinical efficacy, cost savings, and improved patient and physician satisfaction. Removable walking

Table 2—*Percent pressure reduction compared with baseline and location of forefoot pressure sites*

	Patients with first metatarsal ulcers			Patients with second through fifth metatarsal ulcers			Patients with great toe ulcers		
Treatment group	Ulcer site	Second through fifth metatarsals	Great toe	Ulcer site	First metatarsal	Great toe	Ulcer site	First metatarsal	Second through fifth metatarsals
TCC	84.3	79.0	79.3	83.5	81.5	69.1	80.9	77.7	81.2
DH Pressure Relief Walker	82.1	73.3	72.7	83.9	73.0	64.8	76.9	79.8	76.9
Aircast Pneumatic Walker	72.5	57.8	67.0	70.9	67.1	51.6	59.9	69.4	68.5
3D Dura-Stepper	68.5	51.9	79.8	63.0	52.2	79.8	70.0	59.2	62.6
CAM Walker	55.5	51.9	40.8	57.9	46.8	45.0	56.0	50.1	56.5
Xtra Depth Shoe	11.6	18.1	5.9	26.0	22.2	3.8	31.0	9.2	17.5

Data are percent change from baseline measurements in canvas oxford shoes.

casts may be a useful treatment alternative that can be used effectively by primary care physicians and foot specialist alike to treat high-risk patients.

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